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# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

		Application Number	09/546,573
		Filing Date	April 10, 2000
		First Named Inventor	Holten-Andersen, Mads, et. al.
		Group Art Unit	1642
		Examiner Name	Rawlings, S.
Total Number of Pages in This Submission		Attorney Docket Number	19829000310

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## ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Assignment Papers (for an Application)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input checked="" type="checkbox"/> Amendment / Response	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
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<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
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<input type="checkbox"/> Response to Missing Parts/ Incomplete Application		
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		
Remarks		The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP Kevin Bastian	
Signature		
Date	June 5, 2001	

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Typed or printed name	Jill R. Clarke
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TOWNSEND and TOWNSEND and CREW LLP  
By: Jill R. Clarke  
Jill R. Clarke

PATENT  
Attorney Docket No.: 019829000310  
Client Reference No.: 96-185-4

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6-16-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HOLTEN-ANDERSEN, MADS

Application No.: 09/546,573

Filed: April 10, 2000

For: TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES TYPE-1 (TIMP-1) AS A CANCER MARKER

Examiner: Rawlings, S.

Art Unit: 1642

RESPONSE TO RESTRICTION REQUIREMENT

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Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The following is offered in response to the Office Action mailed April 5, 2001. Applicants elect with traverse to prosecute the claims of Group I (claims 1-5, 13-19, 27, and 37) drawn to methods of determining whether a person is likely to have cancer by determining TIMP-1 levels in a sample. Applicants particularly traverse the restriction between Group I and Group III (claims 1-5, 13, 14, and 28-37), drawn to methods of detecting early stage cancer by determining TIMP-1 levels in a sample.

According to the MPEP, where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. See, the MPEP at 803.01. In establishing that an "undue burden" would exist for co-examination of claims, the Examiner must show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. To show undue burden resulting from searching difficulties, the Examiner must show that the restricted groups have a separate classification, acquired a

separate status in the art, or that searching would require different fields of search (MPEP at § 808.02).

In the present restriction, all the groups are indicated as classified under Class 435 subclass 7.23 or class 204, subclass 450. The Examiner has provided little or no reasoning to show that the groups meet the other two criteria required under §808.02. Instead, the Examiner simply states that, as between Groups I and III, the objectives are different. The Examiner does not explain why the different objectives (detection of the likelihood of cancer vs. the detection of early stage cancer) would lead to different searches.

In addition, applicants note that claims 1-5, 13, 14, and 37 have been placed in both Groups I and III. The courts have long held that an Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions. *See, In Re Weber, Soder and Boksay* 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

The courts have definitively ruled that the section of the patent statute authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I and In Re Haas II*. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In Re Weber, Soder and Boksay*:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

*See, In Re Weber, Soder and Boksay* at 334.

In light of the above, Applicants respectfully request that the restriction be withdrawn. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (415) 576-0200.

Respectfully submitted,

  
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